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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 12/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/766,154

Applicant(s)

PATIENCE, CLIVE

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28,29,31,32,34-41,43-45,47-49,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28,29,31,32 and 34 is/are allowed.
- 6) ☒ Claim(s) 35-41,43-45,47-49,51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/03 has been entered. As requested the amendment filed on 6/26/03 and the declaration also filed on 6/26/03 have been entered and considered. Claims 1-25, 30, 46, and 50 have been canceled, and new claims 53-58 have been entered. Claims 28-29, 31-32, 34-41, 43-45, 47-49, and 51-52 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code not included in this action can be found in the previous office action.

#### ***Claim Rejections - 35 USC § 112***

The rejection of previously pending claims 28-32, 34-41, and 43-52 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn in view of applicant's amendments to the claims and arguments.

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The rejection of previously pending claims 28-32, 34-41, and 43-52 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn in view of applicant's amendments to the claims and arguments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-41, and 43-44 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 upon which claims 35, 36, and 39 depend has been amended to recite swine and not animals. Claims 35, 36, and 39 recite both swine in some places, and animals in others rendering the claims indefinite as to the actual species being referred to in the claims. This rejection can be overcome by replacing the recitations of "animals" or "animal" in claims 35, 36, and 39 with "swine". Please note that claims 37-38, 40-41, and 43-55 depend on the claims 35, 36, or 39 and are thus equally rejected for indefiniteness.

Claim 41 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 recites the limitation "said swine in step (b) carrying PERV 3,4 " and "said swine in step (b) carrying PERV 1,2" in claim 39. There is insufficient antecedent basis for these limitations in the claim. Claim 39 refers in step (b) to a first animal

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that carries PERVs present in both of said first and second sets of PERVs but no PERV not present in both of said first and second sets of PERVs, and to a second animal that carries the PERVs present in said first and second sets of PERVs but not present in both of said first and second sets of PERVs. Thus, claim 39 in step (b) refers to an "animal" not a swine and further refers to first and second animals. This rejection can be overcome by amending claim 39 to recite swine instead of animal in step (b), and further by amending claim 41 to recite a first swine and a second swine instead of swine carrying PERVs 3,4 or PERVs 1,2.

***Claim Rejections - 35 USC § 102***

The rejection of claims 45-52 under 35 U.S.C. 102(b) as being anticipated by Kaeffer et al. is maintained and extended to include new claims 53-58. The applicant claims inbred miniature swine of DD haplotype which are inbred so as to remove infectious PERV gene sequences from the genome thereof, and which have been produced by a particular mating and screening process. The applicant further claims a "transplant" comprising tissue or cells derived from these swine. Applicant's arguments and the declaration by Dr. Clive Patience have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant argues that the D/D haplotype swine is not inherently human-tropic PERV free and further that Kaeffer et al. does not teach an inbred population of D/D haplotype swine. In support of this argument, the declaration by Dr. Patience provides data from an experiment which shows that out of 69 D/D/ haplotype swine tested, 12 had the ability to transmit PERV to

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human cells. Based on the data provided, however, it is clear that the overwhelming majority of the D/D haplotype swine do not comprise human-tropic PERV. Further, as noted in previous office actions, the applicant states in their specification that the miniature D/D haplotype swine does not naturally contain human-tropic PERV (specification, page 18, Table 2, page 28, Table 4). Based on the statements in the specification, and the declaratory data, it is clear that while the population of D/D haplotype swine is mixed in terms of possessing human-tropic PERV, the majority of the D/D haplotype swine are in fact human-tropic PERV negative. Kaeffer et al. teaches miniature D/D haplotype swine from a herd of swine bred since 1985 at Nouzilly (Kaeffer et al., page 732). Thus, contrary to the applicant's arguments, Kaeffer et al. does in fact teach an inbred herd of swine. Further, since Kaeffer et al. teaches a herd of swine, and not just a single swine, the teachings of Kaeffer et al. read on numerous D/D haplotype swine. In view of the applicant's own data which shows that the majority of D/D haplotype swine do not have human-tropic PERV, the skilled artisan would recognize that the herd of D/D haplotype swine taught by Kaeffer et al. include swine which are in fact human-tropic PERV negative. As stated in the previous office actions, "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). In the instant case, since the herd of D/D haplotype swine taught by Kaeffer et al. include swine which are in fact human-tropic PERV negative, the product of the art and the product of the instant invention have the same structure. The MPEP states that, when the claimed and prior art products are identical or substantially identical in structure, a *prima*

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*facie* case of either anticipation has been established. MPEP 211.01 and *In re Best*, 195 USPQ 430, 433 (CCPA 1997). Therefore, Kaeffer et al. continues to anticipate the claims as written.

In regards to the new claims which recite a “transplant” comprising organs, tissues, or cells from a swine which is human-tropic PERV negative. Kaeffer et al. teaches isolated spleens and isolated splenocytes from D/D haplotype swine (Kaeffer et al., page 733). Please note that the use of a product for a particular purpose, in this case as a “transplant”, is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that, “.. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). Thus, by teaching all the limitations of the claims as written, Kaeffer et al. anticipates the instant claims.

#### ***Allowable Subject Matter***

Claims 28-29, 31-32, and 34 are considered free of the prior art of record and allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's

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supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

**Please note that the United States Patent and Trademark Office will begin to move to the new campus in Alexandria, Virginia, in December 2003. The examiners of Art Unit 1632 will be moving in January 2004. As of January 13, 2004, this examiner's phone number will be (571) 272-0737, and that of the examiner's supervisor will be (571) 272-0734.**

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

